(54) Title: PHYSIOLOGICAL HEART PUMP CONTROL

(57) Abstract: A blood pump (20) is joined in parallel flow between the left ventricle (16) and aorta (18) of a patient's heart (12). The pump (20) includes an inlet pressure sensor (22) and cooperating controller (30) for measuring inlet pressure to the pump to control operation thereof. The controller (30) adjusts speed of the pump (20) in a closed loop control (40) using feedback of the measured inlet pressure (P1) to conform operation of the pump with the natural cycle of the heart.

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1   Accordingly, it is desired to provide an improved heart assist pump and control

2   system for supplementing blood pumping of the natural heart in situ.

3   DISCLOSURE OF INVENTION

4   A blood pump is joined in parallel flow between the left ventricle and aorta of a

5   patient's heart. The pump includes an inlet pressure sensor and cooperating controller

6   for measuring inlet pressure to the pump to control operation thereof. The controller

7   adjusts speed of the pump in a closed loop control using feedback of the measured inlet

8   pressure to conform operation of the pump with the natural cycle of the heart.

9   BRIEF DESCRIPTION OF THE DRAWINGS

10   The invention, in accordance with preferred and exemplary embodiments,

11 together with further objects and advantages thereof, is more particularly described in

12 the following detailed description taken in conjunction with the accompanying drawings

13 in which:

14   Figure 1 is a schematic representation of an implanted blood pump and

15 cooperating controller in accordance with an exemplary embodiment of the present

16 invention, with an external monitor for initializing the controller and monitoring

17 performance of operation.

18   Figure 2 is a schematic representation of the feedback control for the blood pump

19 illustrated in Figure 1 in accordance with an exemplary embodiment of the present

20 invention.

21   MODE(S) FOR CARRYING OUT THE INVENTION

22   Illustrated schematically in Figure 1 is a living patient 10 having a dysfunctional

23 heart 12 which lacks normal capability for pumping blood 14 through the arterial branch

24 for all levels of activity from rest to strong exercise. In particular, the left ventricle 16

25 of the heart lacks capability to properly pump blood through the aorta 18 to feed the

26 arterial system.

27   In accordance with the present invention, a blood pump 20 in the form of a Left

28 Ventricular Assist Device (LVAD) is suitably implanted in the chest of the patient closely

29 adjacent to the heart in flow communication between the left ventricle 16 and the aorta

30 18 for supplementing pumping capability of the left ventricle.

31   The blood pump may have any conventional form, and in the preferred

32 embodiment is a rotary or centrifugal pump having a suction inlet joined to the left

33 ventricle and pressure outlet joined to the aorta. Performance of the rotary pump is

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1 conventionally rated by corresponding performance curves in which the flowrate through

2 the pump corresponds with the differential pressure across the pump between the inlet

3 and outlet thereof, and varies as the speed of the rotary impeller increases. Increasing

4 impeller speed generally corresponds with increasing differential pressure and increasing

5 flowrate through the pump.

6   As shown schematically in Figure 1, the pump includes means in the form of an

7 inlet pressure sensor 22 for measuring inlet pressure of the blood flow between the left

8 ventricle and inlet side of the pump. The inlet pressure sensor may have any suitable

9 form such as that disclosed in U.S. Patent 6,171,253 and U.S. Patent 6,367,333, both

10 assigned to the present assignee, and both incorporated herein by reference. In these

11 patents, a flat diaphragm is formed in a cannula through which the blood is channeled

12 into the pump, and strain gauges are mounted on the diaphragm for measuring strain

13 thereof which is indicative of pressure of the blood flow thereat.

14   The inlet pressure sensor 22 and its integral cannula are preferably formed

15 integrally with the blood pump, and a suitable inlet tube or catheter 24 joins the inlet

16 pressure sensor to the left ventricle by being sutured thereto.

17   The blood pump preferably also includes means in the form of an outlet pressure

18 sensor 26 joined to the outlet side of the pump in flow communication with the aorta by

19 an outlet tube or catheter 28 suitably sutured thereto. The outlet pressure sensor 26 is

20 preferably identical with the inlet pressure sensor 22 and uses the flat diaphragm for

21 accurately measuring pressure of the blood flow in the corresponding cannula.

22   In the preferred embodiment, the blood pump 20 includes a brushless DC electric

23 motor which powers its impeller, and a suitable battery supply is preferably implanted in

24 the patient for powering the pump. An electrical processor or controller 30 is also

25 preferably implanted in the patient for controlling all operation of the pump. The

26 controller may have any conventional configuration, and is preferably in the form of a

27 digitally programmable microprocessor of sufficiently small size to be integrated directly

28 with the blood pump for minimizing the overall size thereof.

29   Since the pressures measured by the inlet and outlet pressure sensors 22,26 are

30 absolute pressures, and the blood pressure in the natural heart is a gauge pressure, a

31 reference pressure sensor 32 is preferably also implanted in the patient just below the

32 skin 34, and electrically joined to the controller 30. The reference pressure sensor 32

33 may have any suitable form, such as those disclosed in U. S. Patent Application Serial

34 Number 09/472,708 or Serial Number 10/160,837, both incorporated herein by

35 reference. The reference pressure sensor 32 detects ambient or external atmospheric

36 pressure on the patient's skin which may be readily subtracted by the controller from the

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1   pressure readings of the inlet and outlet pressure sensors for producing gauge pressure

2   readings thereof as desired.

3   Although the purpose of the blood pump 20 is to assist pumping of the left

4   ventricle 16, the mechanical blood pump is quite different in operation and performance

5   from that of the natural left ventricle, and therefore requires suitable control thereof for

6   effective operation which does not further compromise performance of the already

7   dysfunctional heart.

8   In accordance with the present invention, the blood pump and its cooperating

9   components described above create an improved system for assisting blood pumping of

10   the left ventricle in an improved method of physiological control of the pump to conform

11   with the natural operation of the left ventricle. As indicated above, the blood pump 20

12   is joined in parallel flow between the left ventricle and the aorta, and develops a suction

13   inlet pressure which extracts some of the blood from the left ventricle for flow through

14   the pump to the aorta bypassing in parallel the normal flow through the left ventricle

15   itself. However, the left ventricle continues to beat and pump a portion of the total blood

16   flow through the aorta.

17   Since the blood pump effectively sucks blood from the left ventricle, suction

18   collapse of the left ventricle must be prevented for ensuring continuous blood flow into

19   the arterial system.

20   In accordance with the present invention, the inlet pressure sensor 22 provides

21   means for measuring inlet pressure P1 of the blood flow to the pump from the left

22   ventricle. The electrical pressure signal from the sensor 22 is suitably provided to the

23   controller 30 by an electrical connection therebetween, and the controller 30 is preferably

24   configured in suitable software for using the inlet pressure for controlling operation of the

25   pump.

26   Figure 2 is a schematic representation of the control system implemented in the

27   controller 30 of Figure 1 preferably using suitable software. The control system

28   illustrated in Figure 2 includes a conventional summing junction 36 which provides means

29   for comparing the measured inlet pressure P1 from the sensor 22 with a desired or set

30   value thereof to determine a difference or error value therebetween.

31   The summing junction is operatively joined to the blood pump 20 by a speed

32   controller 38 for the electrical motor thereof, which controls motor operation by rotation

33   of the impeller therein. The rotary speed in revolutions per minute (RPM) of the pump

34   20 is adjusted in an inner closed loop control 40 using feedback of the measured inlet

35   pressure P1 to minimize the pressure difference with the setpoint at the summing

36   junction 36.

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1   Closed loop feedback control is conventional, and is used in accordance with the
2   present invention for controlling rotary speed of the blood pump based on the measured
3   inlet pressure P1. In a fundamental or first level of pump control, the desired level of the
4   inlet pressure P1 may be suitably set in the control system, and the inner feedback loop
5   40 is used to control motor speed until the difference or error signal between measured
6   and set pressures is reduced to substantially zero, at which time the measured inlet
7   pressure P1 matches the desired value therefor.
8   Figure 1 illustrates schematically a control panel 42 which is suitably operatively
9   joined to the controller 30 for manually setting initial values therein and specifying desired
10   control of the pump. The panel may be hard wired to the controller, but in the preferred
11   embodiment is joined thereto using a suitable telemetry interconnection through the
12   patient's skin for preventing the need for a surgical opening therethrough.
13   The control panel 42 includes various physician-selected settings for configuring
14   the control system to specific patients, and may also be used for monitoring performance
15   of the system. In accordance with the present invention, the fundamental control
16   parameter is the inlet pressure P1 to the rotary pump which may be used as an
17   approximation or close representation of the Left Ventricular Diastolic Filling Pressure
18   (LVDFP).
19   If the pump is operated with excessive suction pressure at its inlet, the left
20   ventricle may be driven to collapse under the suction pressure which, of course,
21   interrupts blood flow to the patient and requires prompt correction. By monitoring the
22   inlet pressure to the pump, the inner feedback control loop may be used to ensure that
23   the inlet pressure P1, and associated LVDFP, are not excessively low.
24   The control system illustrated in Figure 2 preferably also includes a suitable first
25   limit control or limiter 44 which provides means for limiting measured inlet pressure P1
26   to a first range preselected by the physician for a particular patient, with the first range
27   having a minimum value for preventing excessive suction or negative pressure leading
28   to collapse of the left ventricle.
29   The performance of the rotary pump was test evaluated in cooperation with a
30   simulated left ventricle in the form of a flexible sack pneumatically driven in a pulsatile
31   mock loop configuration. A Donavan mock loop, manufactured by MedQuest Products,
32   of Salt Lake City,. UT, USA was used to represent the left ventricle and circulatory
33   system. A centrifugal pump, model EG0024/F, manufactured by Micropump, Inc., of
34   Vancouver, WA, USA withdrew fluid from the apical connection in the ventricle and
35   returned the fluid to the aorta to represent a generic heart assist pump. This pump
36   maintains its impeller speed proportional to a control voltage signal that it receives.

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1   The following Table 1 summarizes the results of thirteen test runs in which the

2   pump inlet pressure setpoint was varied from +10 to -2 mm Hg. The mock loop was

3   configured to simulate left ventricle performance using a 100 mm Hg pneumatic driving

4   pressure applied at 60 beats per minutes (BPM) through a 30% diastole cycle.

5   TABLE 1

LVDFP P1(mm Hg)	Mean Arterial Pressure P2(mm Hg)	LVAD Flowrate (liters/minute)	LVAD Speed (RPM)
10.0	52	4.2	2490
9.0	58	5.0	2720
8.0	64	5.7	2920
7.0	68	6.0	3080
6.0	74	6.7	3250
5.0	79	7.2	3420
4.0	86	7.7	3600
3.0	93	8.1	3780
2.0	102	8.7	4010
1.0	109	9.1	4170
0.0	116	9.5	4320
-1.0	124	9.8	4490
-2.0	136	10.4	4710

21   Table 1 indicates that as the pump inlet pressure P1 decreases, the pump outlet

22   pressure P2 increases along with an increase in pump flowrate and rotary speed of the

23   impeller.

24   The physician may use the known performance of the particular blood pump

25   being used for controlling its operation for specific patient's needs.

26   For example, the control panel 42 illustrated in Figure 1 permits the physician to

27   set the desired inlet pressure P1 for the pump, as well as the corresponding first range

28   for the measured inlet pressure P1, which is +10 to -2 mm Hg, which corresponds with

29   the full range in Table 1, for example. The first level of feedback control provided in the

30   inner loop 40 may then be used to control operation of the pump to achieve the desired

31   setpoint for the inlet pressure P1, with the panel 42 illustrated in Figure 1 showing the

32   actual measured value of the inlet pressure P1 in the corresponding circular indicator.

33   In contrast, the square indicators are used for the various physician programmable values

34   in the control system.

35   The control panel 42 illustrated in Figure 1 also includes a visual monitor which

1   displays the real time performance of the measured inlet and outlet pressures P1,P2 and

2   pump speed in RPM. The exemplary display indicates Level-1 performance in which the

3   RPM gradually increases for correspondingly increasing the outlet pressure P2 of the

4   pump as the inlet or filling pressure P1 decreases, as represented by the minimum or

5   valley portion of the cyclical performance thereof. In the first level (1) control, the

6   measured inlet pressure P1 reached the 3.0 mm Hg desired setpoint value thereof in

7   testing.

8   For Level-1 control, the preselected first range of inlet pressure P1 also includes

9   a maximum value of the inlet pressure so that the right heart, i.e. right atrium and

10 ventricle, is not overburdened by excessive pressure in the left atrium whose pressure

11 is reflected in the filling pressure of the left ventricle.

12   Table 1 indicates that the higher values of inlet pressure P1 correspond with

13 lower values of the outlet pressure P2, flowrate, and pump speed. Since the rotary pump

14 20 is a through-flow device without the complexity of check valves therein, the flowpath

15 through the pump necessarily bypasses the left ventricle to the aorta in parallel flow

16 therewith. Should the rotary pump be operated too slowly, with the output of the left

17 ventricle being greater than that of the pump, the blood from the aorta may flow back

18 through the pump toward the left ventricle in retrograde flow. Accordingly, the setpoint

19 on inlet pressure P1 may be selected by the physician within the selected first range to

20 avoid retrograde flow.

21   Accordingly, the physician has the ability to specify the desired range of

22 operation of the measured inlet pressure P1, including both minimum and maximum

23 values thereof as desired for ensuring proper operation of the pump in conjunction with

24 the beating left ventricle.

25   As indicated above, the control system preferably also includes means in the form

26 of the outlet pressure sensor 26 illustrated in Figure 1 which are operatively joined to the

27 controller 30. In this way, the outlet pressure sensor may be used for measuring

28 pressure of the blood flow from the pump to the aorta in parallel with pumping of the

29 blood from the left ventricle to the aorta.

30   As illustrated in Figure 2, the controller 30 is suitably configured for adjusting

31 speed of the pump in an outer closed loop control 46 using feedback of the measured

32 outlet pressure P2 for maintaining the outlet pressure in a second range preselected by

33 the physician. The outer loop 46 preferably operates in conjunction with the inner loop

34 40, with feedback of the measured inlet pressure P1 being used for maintaining the

35 measured inlet pressure in the first preselected range.

36   The control system illustrated in Figure 2 also includes a suitable second limit

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1   control or limiter 48 configured for effecting the preselected second range of outlet

2   pressure P2, with the control panel 42 illustrated in Figure 1 including corresponding

3   indicators for manually selecting the upper and lower limits on the outlet pressure range,

4   with 110 and 70 mm Hg being illustrated for example, and corresponding with

5   intermediate values of the outlet pressures listed in Table 1.

6   As shown in Figure 2, the outer feedback loop control 46 is configured in a loop

7   to the common summing junction 36 for adjusting the inlet pressure P1 within its first

8   range as implemented by the first limiter 44 for maintaining the outlet pressure P2 within

9   its second range as implemented by the second limiter 48. In this way, both the inlet

10 pressure P1 and outlet pressure P2 may be controlled within physician specified ranges,

11 with primary Level-1 control being based on the inlet pressure P1.

12   In the preferred embodiment, the inlet pressure P1 is measured over a period of

13 at least one full heartbeat cycle, and consists of the minimum value during that period.

14 In this way, the measured inlet pressure corresponds directly with the desired LVDFP in

15 the left ventricle, and is a close approximation thereof.

16   If desired, the control system illustrated in Figure 2 may include suitable means

17 50 for correcting the measured inlet pressure P1 to conform with the diastolic filling

18 pressure inside the left ventricle. Since the inlet pressure sensor 22 is not located

19 directly inside the left ventricle, but closely adjacent thereto, a small difference in

20 pressure therebetween exists. A suitable correction for this difference to better conform

21 the measured inlet pressure P1 to that inside the left ventricle may be effected based on

22 empirical data, or analysis.

23   Similarly, the outlet pressure sensor 26 is located closely adjacent to the aorta

24 18 but not inside the aorta. Accordingly, the pressure measured by the outlet pressure

25 sensor is a close approximation to the arterial pressure inside the aorta, and may be

26 similarly corrected by introducing corresponding means 52 in the outer feedback loop 46

27 of Level-1. The measured value of the outlet pressure P2 may be suitably corrected

28 using empirical data or analysis, as indicated above for the inlet pressure sensor, for more

29 accurately conforming with the arterial pressure inside the aorta.

30   In this way, the two pressure sensors 22,26 provided with the blood pump 20

31 may be used for closely approximating the actual pressures inside the left ventricle 16

32 and inside the aorta 18.

33   Furthermore, since blood pressure is a gauge pressure in practice, the reference

34 pressure sensor 32 illustrated in Figures 1 and 2 is preferably used for measuring the

35 atmospheric reference pressure P3 at the patient's skin 34, which is then used for

36 correcting the measured inlet and outlet pressures P1,P2 to gauge pressure. The

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1   reference pressure P3 is simply subtracted in the controller from the measured values of

2   the inlet and outlet pressures P1,P2 to provide gauge values therefor for better matching

3   the physiological control of the natural heart.

4   The fundamental operation of the Level-1 control is to maintain the left ventricular

5   diastolic filling pressure within a suitable range for effective filling performance of the left

6   ventricle. The filling pressure is the instantaneous minimum pressure per heart cycle.

7   However, the output of the heart must have sufficient blood flow for proper

8   operation of the human body. Correspondingly, the mean arterial pressure in the aorta

9   is indicative of heart performance, and therefore the control system illustrated in Figure

10 2 is configured for using a suitable average of the measured outlet pressure P2 in the

11 control of the pump. As illustrated in the monitor of Figure 1, the instantaneous trace

12 of the outlet pressure P2 is periodic with beating of the heart, but has an average value

13 which may be conventionally determined in the control system for use in controlling the

14 pump.

15   And, the first level control is preferably implemented as an integral proportional

16 feedback control for maintaining the minimum inlet pressure P1 within the physician

17 selected range.

18   Since the outer loop 46 of the Level-1 control is configured for keeping the

19 arterial pressure P2 within the desired programmed limits, it preferably has a slower

20 response time than the inner control loop 40 which uses solely the minimum or diastolic

21 filling pressure portion of the measured inlet pressure P1.

22   The control system illustrated in Figure 1 preferably also includes a second level

23 of control typically associated with the patient undergoing exercise and requiring

24 additional blood flow. Level-2 control is indicated schematically by the reference numeral

25 54 in Figure 2 and is readily incorporated into the control system using additional

26 software.

27   As additionally shown in Figure 1, the physician may specify a resting heart rate

28 (HR) for the patient in terms of beats per minute (BPM). And, as shown schematically

29 in Figure 2, means 56 are provided for measuring or determining the heart rate of the

30 patient's heart which is used for initiating the Level-2 control. When the measured heart

31 rate is greater than the specified resting heart rate, the second level control 54 is

32 effective for increasing speed of the blood pump to correspondingly increase the outlet

33 pressure P2, and thereby provide more blood flow for meeting the increased demand

34 therefor during exercise.

35   When Level-2 control is activated above the resting heartbeat, the second range

36 of outlet pressure P2 is suitably suspended in the second limiter 48, with the second

1   range being suitably replaced by a different preselected third range of the outlet pressure

2   P2 as illustrated schematically in Figure 2 at the second limiter 48.

3   As indicated above, the second range of outlet pressure P2 under Level-1 control

4   includes preselected maximum and minimum values of the outlet pressure. However, for

5   the second level of control, the third range, which replaces the second range, includes

6   a different preselected maximum value of the outlet pressure P2 which is preferably

7   higher than the maximum value in the non-exercise Level-1 control, and a preselected

8   maximum percent (%) increase of the outlet pressure above the outlet pressure at the

9   resting heart rate. Correspondingly, the Level-2 control also includes a preselected

10 maximum permitted increase in the heart rate, all of which values may simply be

11 programmed into the controller at the control panel illustrated in Figure 1 with

12 corresponding square indicators illustrated therefor.

13   In the preferred embodiment, the outlet pressure P2 in Level-2 control is

14 increased linearly in response to increase in the measured heart rate as derived from the

15 physician selected third range of outlet pressure parameters. For example, the physician

16 selects the maximum permitted outlet pressure P2 and the maximum percent increase in

17 outlet pressure above the outlet pressure at the specified resting heart rate. And, the

18 physician specifies the maximum permitted increase in heart rate.

19   Since the outlet pressure at the specified resting heart rate is variable, the actual

20 value thereof is not known until it is measured in situ for a particular patient at the

21 specified resting heart rate. Once the outlet pressure of the specified resting heart rate

22 is measured by the outlet pressure sensor 26, the Level-2 control may then be used to

23 determine or calculate the permitted linear increase thereof within the specified

24 controlling parameters as represented by the HR-P2 graph illustrated in Figure 2.

25   In this way, Level-2 control is initiated above the resting heart rate for increasing

26 the outlet pressure P2 from the pump by adjusting the setpoint of the inlet pressure P1

27 at the common summing junction 36. And, the Level-2 control during exercise includes

28 new limits on the outlet pressure P2 specific to exercise, as opposed to the previous

29 limits imposed by the second limiter 48 during Level-1 control at rest. The blood pump

30 20 is then operated for increasing the outlet pressure P2 to meet the increased demands

31 of patient exercise, while still controlling the blood pump within the specified range of

32 inlet pressure P1.

33   The means 56 for measuring heart rate are illustrated schematically in Figure 2

34 and are preferably effected by measuring the periodic pulses in the measured inlet

35 pressure P1 which corresponds with beating of the heart. As shown in the monitor of

36 Figure 1, the measured inlet pressure P1 has a periodic pulse corresponding with the

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1   heart rate or beating of the heart. The controller may therefore be configured with

2   suitable software for analyzing the inlet pressure signal to discern the beating thereof as

3   represented by the periodic pulses and provide the corresponding heart rate in BPM. In

4   this way, a separate heart rate sensor is not required since suitable information is already

5   available from the instantaneous measuring of the inlet pressure P1.

6   A third level of control 58 is illustrated schematically in Figure 2 and includes

7   suitable means 60 for measuring rotary speed of the pump as expressed in RPM. It is

8   noted that the pump 20 is conventional and typically includes an electrical outlet line that

9   provides a speed signal for the pump using suitable measuring means integrated in the

10 pump itself. Additional outputs for the pump may include the voltage and electrical

11 current for the motor thereof.

12   The third level control 58 further includes means for determining the differential

13 (delta) pressure between the measured outlet and inlet pressures, P2-P1. And then, the

14 flowrate through the pump may be calculated or determined using predetermined

15 performance curves 62 for the pump based on the measured speed and pressure

16 differential.

17   As indicated above, typical rotary pumps have performance curves which plot

18 differential pressure across their outlets and inlets versus flowrate, with different curves

19 for different speeds of the pump impeller. By measuring differential pressure and pump

20 speed, the corresponding flowrate may be readily determined.

21   The Level-3 control is additionally configured for determining pumping power for

22 the blood pump 20 which is the product of the pressure differential and the flowrate. In

23 this way, output power from the pump 20 may be determined, and expressed in watts

24 as indicated in the monitor illustrated in Figure 1.

25   In the preferred embodiment illustrated in Figure 2, the Level-3 control is also

26 operatively joined to the common summing junction 36 for correspondingly adjusting

27 speed of the pump using the same inlet pressure P1 control parameter for controlling

28 pumping power of the pump within the other constraints of the Level-1 and Level-2

29 controls. Although the fundamental control parameter is inlet pressure P1, both the

30 outlet pressure P2 and pump power may be secondarily controlled within the permitted

31 ranges of inlet pressure P1 and outlet pressure P2 as selected by the physician.

32   As shown schematically in Figure 2, the Level-3 control 58 preferably also

33 includes means for determining pumping power for the left ventricle, and then adjusting

34 pumping power of the blood pump 20 to correspondingly share pumping load between

35 the pump and the left ventricle.

36   Pumping power of the left ventricle may be approximated by using the pressure

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1   difference across the ventricular wall as calculated by subtracting the ambient
2   atmospheric pressure P3 from the internal ventricular pressure as approximated by the
3   pump inlet pressure P1. The flow through the ventricle to the aorta is approximated by
4   the flow through the pump 20 as calculated above. The power for the left ventricle is
5   then calculated as the product of this differential pressure and flow, and is determined
6   primarily only during the systolic pumping phase because during the diastolic phase the
7   left ventricle is mostly passively filled.
8   The monitor illustrated in Figure 1 indicates calculated power for the left ventricle
9   and blood pump for an exemplary load division. The control system may be configured
10 in any suitable manner to further modify the inlet pressure P1 control signal for achieving
11 desired load sharing within the permitted ranges of inlet pressure and outlet pressure.
12   It is noted that the three levels of pump control illustrated in Figure 2 all share the
13 common summing junction 36 for adjusting performance of the primary Level-1 feedback
14 control loop 40 for primarily controlling the inlet pressure P1, and secondarily controlling
15 outlet pressure P2 during rest in Level-1 and during exercise in Level-2, and pump power
16 or load sharing in Level-3 within the programmed limits of inlet and outlet pressures.
17   The control system illustrated in Figure 2 may also include a fourth level of
18 control 64 specifically configured for monitoring the inlet and outlet pressures P1,P2, and
19 performance of the pump 20 to diagnose abnormalities therewith. All of the various
20 operating parameters of the pump and associated pressure sensors may be monitored
21 and temporarily stored in suitable memory for use in diagnostic monitoring of system
22 performance for comparing present performance with past performance to diagnose any
23 abnormalities which may develop.
24   The function for the Level-4 diagnostic mode is to monitor for any changes that
25 may lead to LVAD support failure. In one potential failure mode, protein deposition may
26 form on the pumping surfaces and lead to an increased motor current. This increase in
27 motor current may not result in a change in the LVAD flowrate.
28   This trend in pump operating characteristics may be detected by monitoring the
29 trend in the two independently calculated flowrates: (1) the flowrate based on the
30 pressure difference across the pump, and (2) the flowrate estimated from the motor
31 current. The flowrate calculation based on pressures is accurate providing the pump
32 characteristics do not change. It is anticipated that the protein deposition example is
33 most likely to occur in areas of low flow rather than in areas of high flow that determine
34 the pressure versus flow characteristics of the LVAD.
35   Note that it may be possible to measure key values of the operating
36 characteristics during an in vivo pressure calibration procedure, i.e., measure the no-flow

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1   pump head pressures. Also note that the flow calculation based on pressure is not
2   significantly influenced by viscosity over the range of expected viscosities.
3   In another failure mode, the wires connecting the pressure sensors may break
4   resulting in abnormal pressure signals and abnormal flowrate calculations. A histogram
5   of past pressure signal levels and past flowrates may detect this failure mode. In case
6   of a pressure sensor failure, the motor current may be used as a backup parameter to
7   control the pump. Prior to the pressure sensor failure, correlation of the motor current
8   history with the corresponding pump speed and pump pressures histories may result in
9   a useable operating relationship.
10   The various levels of control of the heart pump 20 introduced above permit a
11   physician to tailor pump performance to individual patient condition and needs. These
12   levels of control are arranged in a preferred hierarchy fundamentally using the inlet
13   pressure P1 between the heart and the pump for effective physiological control of the
14   pump to complement natural performance of the heart.
15   The primary strategy for the multiple-level control algorithms used to implement
16   the hierarchical control is to use the physiologic information provided by the pressure
17   sensors to mimic the patient's natural physiologic control system. In particular, the
18   strategy is to fulfill the following three basic heart functions:

19   1)   BALANCE OUTFLOW WITH INFLOW

20   Level-1 contains the primary control loop that regulates the left ventricle diastolic
21   filing pressures within an acceptable operating range selected by the physician. By
22   controlling the left ventricle diastolic filling pressures on a beat-to-beat basis, the resulting
23   LVAD speed profile maintains a flow balance such that the average LVAD pumped flow
24   together with the average native heart output flow is equal to the average return flow to
25   the left heart.
26   By controlling the diastolic filling pressure, the physiologic control algorithm is
27   simulating the control initiated by the stretch receptors in the left ventricle in accordance
28   with the conventional Frank-Starling principle.

29   2)   MAINTAIN ADEQUATE ARTERIAL PRESSURE

30   Level-1 contains the secondary control loop that regulates the mean arterial
31   pressure within acceptable operating range. By controlling the range of the mean arterial
32   pressure, the physiologic control algorithm is simulating the control initiated by the

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1   baroreceptors in the arterial system.

2   3)   MAINTAIN ADEQUATE CARDIAC OUTPUT DURING EXERCISE

3   The principle for the Level-2 physiologic control algorithm is the use of heart rate
4   as physiologic indicator based on sympathetic nervous system regulation of the
5   circulation system during exercise or stress. The blood flow to exercising muscles
6   increases much more as a function of increased blood pressure than as a function of
7   heart rate alone. The typical increase in mean arterial pressure is up to approximately
8   30% during exercise.

9   However, because the left ventricle is compromised, the LVAD patient is not able
10   to increase his/her heart output in response to exercise. By controlling the increase in
11   mean arterial pressure during exercise, the physiologic control algorithm is simulating the
12   control of the sympathetic nervous system.

13   The method disclosed above may be used to control a heart assist pump using
14   blood pressure as a physiologic control variable. Two pressure sensors are used to
15   provide blood pressure inputs for this control algorithm. They are typically mounted on
16   the inlet and outlet of the heart pump, such as a Left Ventricular Assist Device.

17   The direct inputs to the physiologic control algorithm preferably include the LVAD
18   inlet pressure and the LVAD outlet pressure. And, additional inputs may also include the
19   LVAD motor speed and the LVAD current.

20   Another, indirect, input is the heart rate, which can be derived from the LVAD
21   inlet pressure. The output of the physiologic control algorithm is the LVAD speed control
22   voltage. The hierarchy of the inputs and their allowable ranges defines the control space
23   for the above inputs. The physiologic control algorithm functions are preferably divided
24   into four Levels associated with physiological control of the heart.

25   Level-1 is the primary control loop that regulates the left ventricle diastolic filling
26   pressures within an acceptable operating range selected by the physician. By controlling
27   the left ventricle diastolic filling pressures on a beat-to-beat basis, the resulting LVAD
28   speed profile maintains a flow balance such that the average LVAD pumped flow
29   together with the average native heart output flow is equal to the average return flow to
30   the left heart.

31   The Level-2 and Level-3 control algorithms provide additional outer feedback to
32   modulate the Level-1 primary loop feedback control. The Level-2 control algorithm tries
33   to increase the arterial pressure by increasing pump speed based on increased heart rate.
34   Increased arterial pressure results in increase blood flow to those muscle tissues with

1   dilated arterioles, e.g., during exercise. The increase in pump speed can only occur if the

2   left ventricle diastolic filling pressure is maintained within its acceptable range.

3   The Level-3 control algorithm tries to control the pump speed so as to adjust the

4   hydraulic pump power relative to the left ventricular hydraulic power. Again, any change

5   in pump speed can only occur if the left ventricle diastolic filling pressure is maintained

6   within its acceptable range. Preferably only one higher mode Level, e.g., Level-2 or 3

7   may be selected at any one time.

8   To maintain stability to the overall system, the response time for Level-1 is faster

9   than the response times for Level-2 and Level-3. Level 4 is a diagnostic mode that

10   detects abnormal events or abnormal trends in pump and cannulae performance or in left

11   ventricle performance.

12   The Level-1 input control space variables are defined as follows. The primary

13   control variable measures diastolic filling pressures derived from the LVAD input pressure

14   sensor. The secondary control variable measures average arterial pressure derived from

15   the LVAD output pressure sensor.

16   The basic principle for the Level-1 physiologic control algorithm is the use of left

17   ventricular filling pressures to mimic the functional principle of the Frank-Starling

18   mechanism applied to the left heart. Thus within physiological limits, the left heart and

19   the LVAD pump all the blood received into the left ventricle without allowing excessive

20   damming or excessive suction that can lead to collapse of the left ventricle.

21   The primary controlling parameter for this Level-1 algorithm is the diastolic

22   pressure during the left ventricular pressure cycle. The minimum diastolic pressure may

23   be used rather than the end diastolic pressure to prevent ventricular collapse because the

24   LVAD inlet is continuously pumping from the apex of the left ventricle.

25   The rules defining Level-1 control are as follows:

26   The primary rule states that the primary control variable must stay within a range

27   selected by the physician.

28   The secondary rule states that the secondary control variable may stay within

29   non-exercise range selected by the physician providing the primary rule is not at a

30   boundary.

31   The tertiary rule states that the primary control variable may stay at a fixed value

32   selected by the physician provided the primary rule and the secondary rule are not at

33   their boundaries. The tertiary rule may evolve into an adaptive strategy for selecting a

34   relatively optimal diastolic filling pressure that may vary with time based on the patient

35   status. Based on preliminary observations, optimal value may be defined as the minimum

36   area in the two-parameter control space, i.e., minimize any localized instability in the

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1   primary versus secondary parameter control space in a given time.

2   The Level-2 input control space variable is heart rate as preferably derived from
3   the input pressure sensor. The principle for the Level-2 physiologic control algorithm is
4   the use of heart rate as physiologic indicator based on sympathetic nervous system
5   regulation of the circulation system during exercise or stress.

6   The blood flow to exercising muscles increases much more as a function of
7   increased blood pressure than as a function of heart rate alone. The typical increase in
8   mean arterial pressure is up to approximately 30% during exercise. However, because
9   the left ventricle is compromised, the LVAD patient is not able to increase his/her heart
10   output in response to exercise. Therefore the heart rate signal is used to increase pump
11   speed resulting in higher arterial pressure.

12   The physician makes this selection of the actual relationship, e.g., linear increase
13   in mean arterial pressure as heart rate increases (with limit values on mean arterial
14   pressure and heart rate). The Level-2 control monitors the arterial pressure and compares
15   it with the desired arterial pressure that is based on the measured heart rate and derived
16   from the linear relationship mentioned above between heart rate and mean blood
17   pressure. The difference signal multiplied by a constant is then used as a negative input
18   to the Level-1 primary control variable. The interaction of Level-2 with Level-1 is shown
19   schematically at the summing junction 36 in Figure 2.

20   The Level-3 input control space variables use measured pressures and pump
21   speed to determine LVAD and left ventricle hydraulic pumping power in watts. The
22   function of the Level-3 control algorithm may be to control the hydraulic output power
23   produced by the LVAD to a not-to-exceed value or a fixed percentage of total hydraulic
24   work that is predetermined by the physician to prevent the left ventricle from work
25   overload.

26   Another option for controlling the pump power may be to fix the left ventricle
27   power at a constant level selected by the physician. The Level-3 control algorithm may
28   also be used by the physician to temporarily decrease the hydraulic output power
29   produced by the LVAD during controlled exercise periods. This function may be used to
30   condition the left ventricle.

31   Another application for Level-3 is the ability to monitor the left ventricular power
32   during controlled treadmill exercises. This function permits the physician to monitor the
33   recovery of the heart muscle or its deterioration.

34   Note that the left ventricular power calculation is only accurate when the aortic
35   valve does not open during LVAD assist. Opening of the aortic valve may be detected
36   by the presence of the dicrotic notch in the arterial waveform. The dicrotic notch results

1   from the back-flow created pressure during closing of the aortic valve.

2   The LVAD pumping power is the pressure differential (outlet minus inlet pressure)

3   multiplied by the estimated flowrate. The estimated flowrate is obtained using the

4   pressure differential across the LVAD, the rotary speed, and the LVAD pressure versus

5   flow characteristics as a function of the control voltage input. Note that the fluid

6   flowrates for a centrifugal pump are primarily related to the momentum rather than the

7   viscosity, so that physiological changes in blood viscosity may be ignored.

8   The Level-3 control is an outer loop control that modulates the control signal to

9   the Level-1 control loop. For example, the difference in power between the desired value

10   and the calculated value is multiplied by a given constant and then may be used as a

11   negative input to the Level-1 primary control variable. The interaction of Level-3 with

12   Level-1 is shown at the summing junction 36 in Figure 2.

13   The Level-4 diagnostic capability is described above, and is effective for

14   monitoring the various signals generated in the control system.

15   The goal of the control system is to permit a cardiac challenged patient to return

16   to home or work with an improved level of activity and quality of life. The primary aim

17   of the physiologic controller is to prevent the heart from being overstressed while at the

18   same time to condition the heart to encourage partial recovery of heart function. The

19   secondary aim of the physiologic controller is to provide a non-invasive method for the

20   physician to assess heart function via passive and active stress testing and assess

21   functional integrity of the pump and cannula.

22   The objectives of the physiologic control algorithms are the following:

23   1) DEMAND MODES: The Level-1 mode for the physiologic controller algorithm

24   adjusts the impeller speed so that the blood pump meets the patient's flow requirements

25   related to the capability of the native heart. The primary pressure input to the

26   physiologic controller is the left ventricular diastolic filling pressure (LVDFP) that may be

27   derived from the pump input pressure sensor signal. The secondary pressure to the

28   physiologic controller is the aortic pressure (AoP) that may be derived from the pump

29   output pressure sensor signal.

30   The primary pump speed control rule is to maintain the LVDFP at a desired

31   selectable value within selectable limits. The secondary pump speed control rule is to

32   maintain the AoP within a desired selectable range. If the AoP approaches a limit, then

33   the LVDFP value is allowed to change value within its selectable range. Thus the primary

34   LVDFP range takes precedence over the secondary AoP range.

35   The Level-2 mode for the physiologic controller algorithm adjusts the impeller

36   speed (always staying in the Level-1 range for the LVDFP) so that the AOP increases

1   with the heart rate as derived from the input pressure sensor. The controller 30

2   preferably also include a left ventricular collapse detection algorithm and a retrograde

3   flow detection algorithm. Note that flow can be calculated using the pressure differential

4   across the blood pump 20 in conjunction with the rotary speed and the pressure versus

5   flow characteristics of the pump.

6   2) CONDITIONING MODES: The Level-3 mode for the physiologic controller

7   algorithm adjusts the impeller speed so that the pump may provide conditioning of the

8   native heart by providing programmed periods of time where the pump reduces its

9   hydraulic power.

10   The physiologic controller algorithms use the pressure input and output

11   measurements to calculate the pump hydraulic power as well as the native heart

12   hydraulic power (when the aortic valve is closed). The physician can program the Level-3

13   mode to correspond to a passive conditioning mode or active conditioning mode. The

14   Level-3 mode is always constrained to be within the boundary of the Level-1 primary

15   parameter range.

16   3) PATIENT DIAGNOSTIC MODE: The physician may monitor the native heart

17   power and pump power (as calculated by the physiologic controller algorithm) to monitor

18   the patient during controlled exercises on the treadmill. The Level-4 diagnostic mode

19   permits the physician to periodically measure trends in recovery or deterioration due to

20   disease progression.

21   4) PUMP AND CANNULAE DIAGNOSTIC MODE: The pressures measured at the

22   inlet and outlet of the pump as well as the flow calculation derived from the pressure

23   measurements provides primary diagnostic capability for detecting flow blockages. A

24   pump diagnostic method for measuring performance changes of the blood pump 20 is to

25   compare the flow derived from the pressure measurements with the flow derived from

26   the motor current. It is anticipated that trend data may provide an early warning of

27   impending failure.

28   The pump and cannula diagnostic mode is designed to detect abnormal pressures

29   such as those generated by flow blockages or by defective subsystems. The control and

30   diagnostic algorithms have been tested via simulation of these abnormal conditions on

31   the mock loop.

32   For the first level control, an integral proportional pump control algorithm uses

33   as the control input the LVDFP as represented by the measured inlet pressure P1,

34   preferably the corrected gauge pressure. The controller compares the measured inlet

35   pressure to a setpoint and uses the difference as an error signal.

36   The error signal is integrated with respect to time and multiplied by a suitable

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1   value K. In equation form, the basic control is: d/dt(Flow) = K * (inlet pressure -

2   setpoint pressure); that is, the rate of change in flow pumped through the blood pump

3   is calculated by multiplying K times the error.

4   In one embodiment, K is a constant. A good value for this constant has been

5   experimentally found to be approximately K = 0.1 liter/min/sec/mmHg. For example, if

6   the error signal indicated that the inlet pressure was too high by 10 mmHg, the flowrate

7   would be increased by 1 liter/min each second to correct it.

8   In another embodiment, K is a function of the error. In this embodiment K is

9   larger when the error is smaller. In particular, K is larger when the error is less than zero.

10 For example, there may be two values of K: K+ and K-. The positive value K+ is used

11 when the error is positive and the negative value K- is used when the error is negative.

12 K- should have a value smaller than K+.

13   The effect of the higher value of K- is that the system reacts more quickly to low

14 pressures in the ventricle to avoid the dangerous condition of suction and collapse of the

15 ventricle. For example, if K- = - 0.2 liter/min/sec/mmHg, and the inlet pressure were

16 too low by 10 mmHg, the flow would decrease by 2 liter/min each second. Low

17 pressures in the ventricle signal imminent collapse of the ventricle. The more rapid

18 reduction in pumping rate in response to low pressures would make it more likely that the

19 collapse of the ventricle would be avoided.

20   The effect of the lower value of K+ is that the system reacts more slowly to high

21 pressures in the heart. There is no urgency to correct the inlet pressure when it is too

22 high. For example, for the lower value of K+ = 0.02, if the pressure were too high by

23 10 mmHg, the pumping rate would increase more slowly, only by 0.2 liter/min each

24 second. The slower rate of increase would prevent overshoot and stabilize the overall

25 control algorithm. The net result of this combination is that the composite algorithm is

26 fast enough to be safe and slow enough to be stable.

27   The usefulness of such a fast algorithm was demonstrated on tests on the mock

28 loop describe above. The ventricle component of the mock loop was brought from the

29 normal, uncollapsed condition to the collapsed condition by suction caused by the pump

30 pumping too hard.

31   The collapse could be done repeatably by increasing the pump speed to deliver

32 approximately 10 liters per minute. Furthermore, a fluttering instability reported in calf

33 experiments has been repeated in this experimental setup. Fluttering instability of the

34 left ventricle may be represented by exposing the ventricle to suction pressures between

35 −50 mmHg and −250 mmHg, with oscillation between these two pressures. These

36 experiments only approximate the quantitative pressures expected in a real heart,

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1   however, it appears that the qualitative mechanism of the instability has been identified

2   in these experiments.

3   The instability appears to follow this sequence:

4   1)   An excess pumping speed causes suction pressures in the ventricle;

5   2)   The ventricle walls close together, and partially block off the pump inlet

6   cannula;

7   3)   A large, negative pressure spike appears in the ventricle, caused by:

8   a)   The pump dead-ending against the flow cutoff at the inlet, and

9   b)   The momentum of the column of blood coming to a sudden stop.

10   4)   After stopping, the column of fluid bounces backward, being pulled back

11 by the large negative pressure spike in the ventricle;

12   5)   The backward motion reopens the closed ventricle, allowing forward flow

13 resume; and

14   6)   Steps 1-5 repeat.

15   A controller is needed to avoid the excess pumping speed that causes the suction

16 pressure in step 1. If for some reason, the suction in step 1 does occur, the controller

17 should be able to react quickly enough to avoid step 2, the ventricle collapse.   This

18 shows the importance of both controlling the pressure and responding quickly to reduce

19 pump speed in response to suction in the ventricle.

20   A method has also been developed to use pressure measurements to monitor the

21 hydraulic power produced by the ventricle. Hydraulic power of the heart is the pumping

22 power that actually goes into the blood, and it is a measure of how hard the heart is

23 working. It is pressure times the volume flowrate.

24   For the heart, the relevant pressure is the difference between ventricular pressure

25 (inside the heart) and the pressure outside of the heart muscle wall. This pressure is a

26 measure of how hard the heart is squeezing. The flowrate is a measure of how much

27 volume the heart is squeezing. The product of flowrate times pressure is a measure of

28 how much hydraulic power the heart is producing.

29   Note that only the flow that goes through the pump is being measured. If the

30 ventricle pumps faster than the pump, the excess flow goes out of the aortic valve in the

31 normal manner, and this excess flow is not accounted for in the calculation of hydraulic

32 power. In such cases, this method of calculating ventricular power may be considered

33 as an estimate of the minimum power.

34   In this calculation of heart power, in one method only the power during the

35 systolic phase is calculated.   The systolic phase can be defined as the portion of the

36 pumping cycle in which the ventricular pressure is above a measured diastolic level, e.g.,

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1   to prevent excessive negative pressures in the ventricle, to avoid retrograde flows in the
2   pump, and to auto-regulate the pump impeller speed to maintain arterial pressures
3   appropriate for patient exercise level and perfusion needs.
4   The algorithms may also use the pressure sensor inputs for advanced monitoring
5   of heart assist devices. The algorithms convert measured values of pressure into
6   calculated values of flowrate and the hydraulic power imparted to the blood by both the
7   pump and the left ventricle. The calculated quantities may be used to detect and monitor
8   abnormal LVAD performance, abnormal ventricular function, and trends in ventricular
9   function and LVAD performance.
10   The pressure sensors used in the supporting experiments were developed and
11   manufactured by APEX Medical, Inc. of East Walpole, MA, USA. The basic sensor,
12   referred to as the APEX Pressure Sensor (APS), is both patented and described in a
13   previously published article.
14   The APS uses a pressure-sensing diaphragm that can be integrally built into the
15   wall of any titanium pump or inlet cannula. The pressure-sensing tube can be made with
16   an inside diameter the same as any LVAD inlet cannula. Mounted on the pressure-
17   sensing diaphragm is a molecularly bonded, thin-film strain gage, whose strain measuring
18   elements are located at the points of highest tensile and compressive strain.
19   A Millar MPC-500 MikroTip catheter pressure sensor, made by Millar Instruments
20   of Houston, TX, USA was placed adjacent to the APS for comparison measurement. The
21   flow was measured by a model T110 ultrasonic flow meter, manufactured by Transonic
22   Systems, Inc., of Ithaca, NY, USA. And, the Donavan mock loop was used to represent
23   the left ventricle and circulatory system.
24   The control algorithms used to drive the control module were written in LabVIEW
25   (Laboratory Virtual Instrument Engineering Workbench) version 5.1 software. A DAQPad
26   M10-16XE-50 data acquisition and control module collected the proportional voltage
27   signals produced by the pressure sensors and the flow meter, and generated a
28   proportional voltage output for the pump. Both of the above are sold by National
29   Instruments, Inc. of Austin, TX, USA.
30   The primary goal of Level 1 control is to maintain the Left Ventricular Diastolic
31   Filling Pressure (LVDFP), or Filling Pressure, within a physician programmable range. An
32   integral control algorithm was implemented with pump inlet pressure, which is
33   representative of LVDFP, as the input and pump speed control signal as the output. The
34   purpose of this Level-1 goal is to mimic the functional principle of the Frank-Starling
35   mechanism applied to the left heart.
36   The secondary goal of Level-1 is to optimize the LVDFP within the physician

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1   during some portion of which the mitral valve is open, and some portion of which the
2   ventricle is most susceptible to suction and collapse.
3   An overview of the Level-1 and Level-2 control scheme is shown in Figure 2. The
4   Level-1 control is implemented as a standard integral speed controller with LVDFP, as
5   represented by the measured pressure P1, as the control input and pump speed signal
6   as its control output. The control algorithm for the Level-1 inner loop is designed to
7   maintain the LVDFP within physician programmable limits at a desired physician
8   programmed value when appropriate.
9   The Level-1 outer loop control is based on keeping the arterial pressure, as
10 represented by the measured outlet pressure P2, within programmed limits and has a
11 slower response time than the LVDFP inner control loop. The outer loop changes the
12 effective desired LVDFP setpoint of the nested inner loop when the arterial pressure
13 reaches the programmed limit values. Level-1 effectively controls the LVDFP within a
14 programmed range whenever the arterial pressure reaches a programmed limit and
15 controls the LVDFP to a desired value when the arterial pressure is within limits. Thus
16 the resultant LVDFP value has been optimized because it meets the conditions of both
17 the inner and outer loops.
18   The Level-2 control algorithm is implemented as an outer control loop around the
19 inner Level-1 control loop. The control input to Level-2 is the outlet pressure, and the
20 control output is the modified target LVDFP sent to the Level-1 control loop. When
21 Level-2 is active and the pulse rate is above the programmed threshold, the desired target
22 value for LVDFP is continuously modified to provide the feedback control for the target
23 arterial pressures.
24   Thus the Level-2 mean arterial pressure is controlled through the intermediate
25 mechanism of actively adjusting the Level-1 effective target value of the LVDFP within
26 its programmed range.   Note that Level-1 contains an outer feedback loop for adjusting
27 the Level-1 LVDFP value to maintain the non-exercise mean arterial pressure within the
28 target limits.
29   These non-exercise limits are suspended when Level-2 is activated and replaced
30 by the exercise limits of the mean arterial pressure. Both the non-exercised limits and
31 the exercise limits for the arterial pressures are physician programmable. The Level-2
32 outer loop control algorithm controls the LVDFP to maintain an exercise arterial pressure
33 target value, whereas the Level-1 outer loop controls the LVDFP to maintain a non-
34 exercise arterial pressure range.
35   Table 2 summarizes the priorities that the hierarchical Level-1 and Level-2
36 algorithms use to achieve their goals.

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1   **TABLE 2: Algorithm Hierarchy**

GOAL	LEVEL 1 CONTROL	LEVEL 2 CONTROL
Primary	Keep LVDFP Within Limits	Keep LVDFP Within Limits
Secondary	Keep Arterial Pressure Within Limits	Control to Variable Arterial Pressure Setpoint (based on BPM)
Tertiary	Control to LVDFP Setpoint	

6   The flowrate was calculated based on the measured pressure difference across

7   the pump and the pump performance curves. The pump performance curves were

8   generated by measuring the flow vs. pressure difference at a series of impeller speeds

9   of the pump. These pump curves are a characteristic of a given pump and are generally

10 available from the pump manufacturer.

11   The data from these curves were entered into the LabVIEW program. During

12 subsequent operation of the pump, the unknown value of the flow is calculated from the

13 stored pump data through interpolation on the curves based on the measured pressure

14 difference and the known pump impeller speed.

15   The power was calculated as follows. The definition of hydraulic power of a

16 device is the product of the flowrate through the device times the pressure difference

17 across the device. For the pump, this calculation of power is straightforward. The

18 pressure difference is equal to the measured instantaneous pressure across the pump,

19 P2-P1.

20   The flow through the pump can be measured from a flow meter during lab

21 testing, or can be calculated in situ from pressure using the method described above.

22   For the left ventricle, this calculation of power is more complex. The pressure

23 difference across the ventricular wall is calculated by subtracting the ambient barometric

24 pressure from the internal ventricular pressure, as approximated by the pump inlet

25 pressure, i.e. P1-P3.

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1   The flow out of the ventricle is approximated by the flow through the pump as
2   calculated above. This assumption is valid to the extent that all of the flow exiting the
3   ventricle goes through the pump. When the heart recovers to the extent that the natural
4   pumping is stronger than that of the LVAD, so that substantial flow exits through the
5   aortic valve, this flow through the aortic valve will not be accounted for in this power
6   calculation.

7   The power is accounted for only during the systolic phase, because during the
8   diastolic phase the left ventricle is mostly passively filled, and in any event the diastolic
9   power is negligible with respect to the systolic power. The time history of this
10 instantaneous systolic power can be displayed as a numerical value.

11   The monitor in Figure 1 shows the results of a typical test of the Level-1 control
12 algorithm. Note that the desired inlet pressure was tested at integer values within the
13 range of −2 to +10 mm Hg. The typical test results used a desired inlet pressure of 3.0
14 mm Hg and may be representative of a physician selected setpoint. Each selection of
15 desired inlet pressure resulted in a different set of bypass flow and arterial pressure
16 values for a given peripheral resistance.

17   The plotted values in Figure 1 are representative of the state of the system at the
18 end of the test at time T = 20 seconds. The plot area shows a several second time
19 history to T = 20 seconds of the inlet pressure, the outlet pressure, and the pump control
20 signal, which is representative of RPM. The pump control signal is scaled such that 15
21 mm Hg on the Y-axis corresponds to 1 V (volt) of pump control signal.

22   In this plot, the lower pulsating signal is the inlet pressure P1, the upper pulsating
23 signal is the outlet pressure P2, and the smooth signal is banded between 40 and 60 mm
24 Hg (between 2.67 and 4.00 V) and represents the pump control signal or RPM.

25   Before time T = 3 seconds, the controller was set to manual mode with the pump
26 signal fixed at 3V. At time T = 3 seconds, the Level-1 control was enabled to bring the
27 LVDFP to desired constant value of 3.0 mm Hg that was defined in the corresponding
28 square indicator box.

29   Once enabled, the controller increased the pump signal to bring the LVDFP (seen
30 as the valley in each inlet pressure pulse) from its uncontrolled initial value of
31 approximately 6 mm Hg to the specified value of 3.0 mm Hg. The pump signal increased
32 from its initial voltage of 3.00 V to a final steady state value of 3.77 V that corresponds
33 to an initial pump speed of 3000 RPM (revolutions per minute) and a final pump speed
34 of 3770 RPM.

35   The increased pump speed caused the time averaged outlet pressure to increase
36 from its initial value of 68 mm Hg to the final value of 103.6 mm Hg. This exact value

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1   of 103.6 appearing in the corresponding circular indicator box is computed from a time

2   averaging of the pulsing pressure over one complete heartbeat cycle. From the history

3   plots, the characteristic response time of the system is seen as approximately 5 seconds.

4   Table 1 summarizes the results for 13 test runs as indicated above.

5   Figure 1 also shows sample setpoint values for the cooperating Level-2 control

6   algorithms. The measured heart rate or pulse rate is 60 BPM as shown in the

7   corresponding circular indicator box. This value is below the specified Resting Heart Rate

8   value of 61 BPM as set in its corresponding square indicator box; so that the Level-2

9   control algorithm is below its threshold for controlling the exercise target values of mean

10 arterial pressure.

11 In one test, the heart rate was increased to 99 BPM, representing an increase that

12 could be caused, for example, by the patient engaging in physical exercise. The increase

13 in heart rate above the threshold increases the Level-2 target outlet pressure linearly with

14 heart rate. The heart rate of 99 BPM yields a target outlet pressure of 120 mm Hg. The

15 outer control loop of Level-2 control adjusts the controller setpoint, i.e., adjusts the

16 desired target value for LVDFP, of the inner Level-1 control loop appropriately to bring

17 the actual outlet pressure to 119.4 mm Hg (not illustrated), near its target value of 120

18 mm Hg.

19 In this specific test, the Level-2 controller needed to increase the initial outlet

20 pressure of approximately 100 mm Hg to the target of 120 mm Hg. An increase in outlet

21 pressure corresponds to an increase in pump speed, which corresponds to a decrease in

22 inlet pressure, i.e., a decrease in the desired LVDFP. To reach its target, the Level-2

23 controller decreased the desired LVDFP setpoint of the Level-1 controller from 2.0 to 0.0

24 mm Hg, which, in turn, increased the pump speed signal from 3.10 to 4.36 V, which, in

25 turn, increased the outlet pressure from 100 to 120 mm Hg. This process took

26 approximately 10 seconds. The mean arterial pressure of 120 mm Hg has a limit cycle

27 variation of less than 5%.

28 In another test, the flowrate (in liters/min) was measured through a transonic flow

29 meter, and was calculated from the pressure difference, pump speed, and pump

30 characteristics. The calculated and measured flowrates agreed in mean value, but

31 differed in the higher frequency components. The value calculated from the pressure

32 signal had a higher frequency content and a phase that led the phase of the measured

33 value.

34 Referring to Figure 1, the power from the heart pump and heart are displayed in

35 the lower right corner. Also displayed is the relative contribution of each to the total

36 power output to the blood.

forces acting on axial impeller 2a, is mounted securely and with zero contact relative to housing 9.

An additional bearing of axial impeller 2 that provides magnetic support in a hydrodynamic or fluid dynamic fashion inside housing 9 can be achieved by a number of embodiments. For example, rotor jacket 2 can have a groove on the outer surface facing stator 7, said groove running helically so that a hydrodynamically active step bearing is formed. By virtue of this measure, the flow of fluid f flowing from the pressure side to the intake side is also increased, reduced, suppressed, or deflected, since the fluid located in the gap is delivered depending on the pitch of the helical groove as well as the direction of rotation and the rpm of the rotor. With similar grooves provided on the front of the rotor, the effect of the hydrodynamic bearing acting in the axial direction can likewise be improved.

Figure 6a shows an axial impeller 2a for a stator 7 that operates on the principle of a reluctance motor. Magnetically active rotor part 1 also forms axial impeller 2a, with rotor part 1 being made of a ferromagnetic material but not being permanently magnetized, and with section 1f of rotor part 1 that projects in a cruciform manner having a twist in axial direction A so designed that sections 1f also form blades 1b of axial impeller 2a. The path of sections 1f is correspondingly hydrodynamically optimized so that a thrust acting on the fluid in the axial direction can be produced by these sections 1f. The diameter DR of axial impeller 2a is at least twice as great as the axial height HR of axial

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1 speed, and the ventricular power increases as the pneumatic pressure applied to the

2 ventricle is increased. A correspondence exists between the heart power calculated by

3 this method and the actual function of the ventricle when tested in the mock loop.

4   Tests of control algorithms using APS pressure sensors on standard mock loop

5 hardware demonstrated proof-of-concept that a stable pressure-based controller could

6 be built using such pressure sensors. The Level-1 control algorithm was able to control

7 the pump speed in order to maintain the LVDFP within limits. The Level-2 control

8 algorithm was able to indirectly control the specified outlet pressure to the specified

9 target values provided that the Level-1 LVDFP was within its limits. The flowrate

10 calculated by pressure measurements and pump characteristic curves was able to match

11 the mean value of the measured flowrate. The hydraulic power produced by the pump

12 and by the ventricle were calculated using the pressure measurements and provided

13 useful information for monitoring the relative performance of the rotary assist pump

14 versus the left ventricle.

15   While there have been described herein what are considered to be preferred and

16 exemplary embodiments of the present invention, other modifications of the invention

17 shall be apparent to those skilled in the art from the teachings herein, and it is, therefore,

18 desired to be secured in the appended claims all such modifications as fall within the true

19 spirit and scope of the invention.

pressure to conform with pressure inside left ventricle.

9.   A method according to claim 6 further comprising correcting said measured outlet pressure to conform with pressure inside said aorta.

10.   A method according to claim 6 further comprising:
        measuring atmospheric reference pressure at skin of the patient; and
        correcting said measured inlet and outlet pressures to gauge pressure using said reference pressure.

11.   A method according to claim 6 further comprising:
        specifying a resting heart rate for the patient;
        measuring heart rate of the patient's heart; and
        increasing speed of said pump in a second level of control to increase said outlet pressure for measured heart rate greater than said resting heart rate.

12.   A method according to claim 11 further comprising:
        suspending said second range of outlet pressure when said second level control increases said pump speed; and
        replacing said second range with a different preselected third range of said outlet pressure.

13.   A method according to claim 12 wherein said second level control increases said outlet pressure from said pump by adjusting said inlet pressure.

14.   A method according to claim 12 wherein:
        said second range includes preselected maximum and minimum values of said outlet pressure;
        said third range includes a different preselected maximum value of said outlet pressure, a preselected maximum percent increase of said outlet pressure above said outlet pressure at said resting heart rate, and a preselected maximum increase in said heart rate; and
        said outlet pressure is increased in response to increase in said heart rate as derived from said third range.

15.   A method according to claim 12 wherein said heart rate is measured by

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measuring periodic pulses in said inlet pressure corresponding with beating of said heart.

16.   A method according to claim 12 further comprising:
measuring speed of said pump;
determining pressure differential between said measured outlet and inlet pressures;
determining flowrate through said pump using predetermined performance curves for said pump based on said measured speed and pressure differentials; and
determining pumping power for said pump as the product of said pressure differential and said flowrate determined therefrom.

17.   A method according to claim 16 further comprising adjusting said speed of said pump in a third level of control of said inlet pressure to control pumping power of said pump.

18.   A method according to claim 17 further comprising:
determining pumping power for said left ventricle; and
adjusting pumping power of said pump to correspondingly share pumping load between said pump and said left ventricle.

19.   A method according to claim 12 further comprising monitoring said inlet and outlet pressures, and performance of said pump to diagnose abnormalities therewith.

20.   A system for assisting blood pumping through a left ventricle of a patient's heart comprising:
a blood pump joined in parallel flow between the left ventricle and an aorta inside said patient;
an inlet pressure sensor for measuring inlet pressure of blood flow to said pump from said left ventricle;
a controller operatively joined to said inlet pressure sensor, and to said pump for controlling operation thereof, and including:
means for comparing said measured inlet pressure with a set value thereof to determine a difference therebetween; and
means for adjusting speed of said pump in a closed loop control using feedback of said measured inlet pressure to minimize said pressure difference.
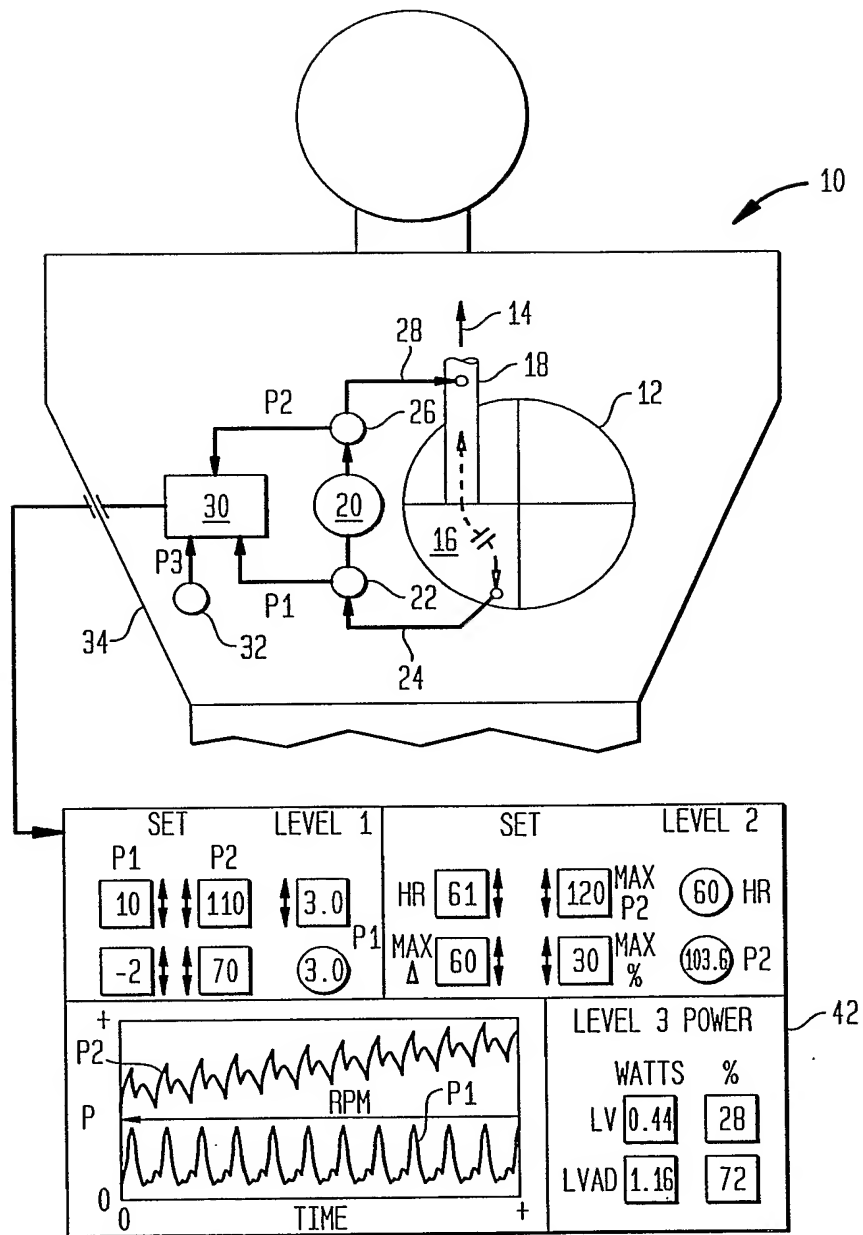
21.   A system according to claim 20 wherein said controller further comprises means for limiting said measured inlet pressure to a preselected first range having a minimum value for preventing collapse of said left ventricle.

22.   A system according to claim 21 further comprising:

an outlet pressure sensor operatively joined to said controller for measuring outlet pressure of said blood flow from said pump to said aorta; and

said controller further includes an outer closed loop control for adjusting speed of said pump using feedback of said measured outlet pressure for maintaining said outlet pressure in a preselected second range, with feedback of said measured inlet pressure being used in a cooperating inner closed loop control for maintaining said inlet pressure in said first range.

23.   A system according to claim 22 wherein said outer loop control is further configured to adjust said inlet pressure within said first range for maintaining said outlet pressure within said second range.

24.   A system according to claim 23 wherein said controller is further configured for measuring said inlet pressure over a period of at least one full heartbeat cycle, and said inlet pressure consists of the minimum value thereof during said period.

25.   A system according to claim 24 further comprising:

a reference pressure sensor disposed adjacent to skin of said patient for measuring atmospheric pressure thereat; and

said controller is further configured for correcting said measured inlet and outlet pressures to gauge pressure using said reference pressure.

26.   A system according to claim 25 further comprising:

means for measuring heart rate of the patient's heart; and

said controller further includes a second level of control for increasing speed of said pump to increase said outlet pressure for measured heart rates greater than a specified resting heart rate.

27.   A system according to claim 26 wherein said controller is further configured for suspending said second range of outlet pressure when said second level control increases said pump speed; and

determining pumping power for said left ventricle; and

adjusting said pumping power of said pump to correspondingly share pumping load between said pump and said left ventricle.

FIG. 1

10

14
28
18
12
P2
26
P3
30
20
16
32
P1
22
24
34

SET	LEVEL 1	SET	LEVEL 2

P1   P2

10   110   3.0

-2   70   (3.0)   P1

HR   61   120 MAX P2   (60) HR

MAX Δ   60   30 MAX %   (103.6) P2

+
P2
P
RPM
P1
0   TIME   +

LEVEL 3 POWER   42

WATTS   %

LV 0.44   28

LVAD 1.16   72

FIG. 2